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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,658	08/13/1999	Luisa Iruela-Arispe	1448.1070006	2817

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/373,658	Iruela-Arispe et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Mar 20, 2000* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3 months* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s):
see attached

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *24-37 and 46-68*

Claim(s) objected to: *none*

Claim(s) rejected: *38-45 and 69-85*

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .

10. ☐ Other:

Response to Arguments

1. The rejection of claims 38-56 and 67-85 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

2. Applicant argues that a single use is all that is required for a claimed invention to meet the utility requirement. Applicant asserts that polynucleotides having 95% sequence identity can be used as probes for SEQ ID NO:1. Applicant argues that the examiners statement of the Office action of May 10, 2001 is misplaced as the claims are drawn to polynucleotides not polypeptides, therefore, a rejection based on lack of enablement of the proteins encoded thereby, is inappropriate. All of the above arguments have been considered but not found persuasive.

Claims 38-56 are drawn to polynucleotides at least 30 nucleotides in length which hybridizes to nucleotides 466 to 3366 of SEQ ID NO:125. Claims 67-76 are drawn to polynucleotides of at least 30 nucleotides in length which hybridize to nucleotides 1-2853 of SEQ ID NO:1. Claims 77-85 are drawn to polynucleotides having 95% sequence identity to SEQ ID NO:1. Irrespective of whether or not it is the applicants intention of claiming other coding sequences, the claim still encompasses polynucleotides which encode alternate polypeptides from the disclosed SEQ ID NO:2 and 126.

Applicants argument that they have enabled a use for the variant polynucleotides by claiming that they could be used as probes for SEQ ID NO:1 and 125 is not persuasive. In order to satisfy the enablement requirement of 35 U.S.C. 112, first paragraph, the use must also satisfy the utility requirement of 35 U.S.C. 101, in that the asserted use must be specific, substantial and credible. It is not credible that a polynucleotide variant that hybridized to SEQ ID NO:1 or 125, or a polynucleotide having 95% sequence identity to SEQ ID NO:1 or 125 would be used as a probe for SEQ ID NO:1 or 125.

Applicant argues that "one of ordinary skill in the art would be able to screen polynucleotides and determine, without undue experimentation, whether a given polynucleotide falls within the scope of the claims". This has been considered but not found persuasive, as the claim encompass any polynucleotide, regardless of function, which hybridizes or has 95% sequence identity to SEQ ID NO:1 or 125. The claims fail to limit the scope of the variant nucleotides by specifying a function for said variants.

Applicant argues that the variant polypeptides have utility in that they can be used to encode proteins which are capable of generating antibodies against the disclosed METH proteins of the instant invention. Applicant agues that as the antigenic regions of the METH1 protein have been identified in the specification, one of skill in the art would be able to vary the encoded protein without altering the antigenic regions of said variant protein. This has been considered but not found persuasive. Immunogenic regions are responsible for raising an antibody in host. The antigenic regions of a protein differ from the immunogenic regions and antigenic regions need not be immunogenic regions. Thus, polypeptides comprising said antigenic regions would not be useful for the generation of antibodies which bind to the disclosed SEQ ID NO:2. For the same reasons as stated above it is not credible that one of skill in the art would select a variant polypeptide to generate antibodies to SEQ ID NO:2 or 126 as a variant peptide may not have the immunogenic epitopes of SEQ ID NO:2 or 126 and may comprise immunogenic epitopes not present in SEQ ID NO:2 or 126. Further, the claims do not limit the variant polynucleotides which hybridize to SEQ ID NO:1 or 125, or the variant polynucleotide having 95% sequence identity to SEQ ID NO:1 or 125 as to the function of the encoded polypeptide.

Applicant argue that the specification is enabling for variants of SEQ ID NO:1 and 125 in that the specification teaches that a polypeptide comprising amino acids 549-563 inhibits angiogenesis. Upon inspection of the cited pages and line numbers it can be concluded that the specification teaches a polypeptide fragment consisting of amino acids 549-563 which inhibits angiogenesis. There is no teachings in the specification that would lead one to believe that

transfer of this peptide into any possible amino acid sequence context would preserve the anti-angiogenic properties of the resulting protein. Further, the variant polynucleotides claimed are not limited by function.

Applicant argues that the specification identifies other structural elements of the METH1 protein, such as metalloprotease, disintegrin and TSP-like domains and one of skill in the art would avoid altering the protein sequence in those areas. This is not persuasive as the variant polynucleotides claimed are not limited by function.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANTHONY C. CAPUTA
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Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
June 18, 2002